General

Guideline Title

2012 HRS/EHRA/ECAS expert consensus statement on catheter and surgical ablation of atrial fibrillation: recommendations for patient selection, procedural techniques, patient management and follow-up, definitions, endpoints, and research trial design.

Bibliographic Source(s)

Calkins H, Kuck KH, Cappato R, Brugada J, Camm AJ, Chen SA, Crijns HJ, Damiano RJ Jr, Davies DW, DiMarco J, Edgerton J, Ellenbogen K, Ezekowitz MD, Haines DE, Haissaguerre M, Hindricks G, Iesaka Y, Jackman W, Jalife J, Jais P, Kalman J, Keane D, Kim YH, Kirchhof P, Klein G, Kottkamp H, Kumagai K, Lindsay BD, Mansour M, Marchlinski FE, McCarthy PM, Mont JL, Morady F, Nademanee K, Nakagawa H, Natale A, Nattel S, Packer DL, Pappone C, Prystowsky E, Raviele A, Reddy V, Ruskin JN, Shemin RJ, Tsao HM, Wilber D, Heart Rhythm Society Task Force on Catheter and Surgical Ablation of Atrial Fibrillation. 2012 HRS/EHRA/ECAS expert consensus statement on catheter and surgical ablation of atrial fibrillation: recommendations for patient selection, procedural techniques, patient management and follow-up, definitions, endpoints, and research trial design. Heart Rhythm. 2012 Apr;9(4):632-96.e21. [736 references] PubMed

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Class of recommendation (I, IIa, IIb, III) and levels of class of evidence (A-C) and are defined at the end of the "Major Recommendations" field.

Consensus Indications for Catheter and Surgical Ablation of Atrial Fibrillation (AF)

Indications for Catheter Ablation of AF

- Symptomatic AF refractory or intolerant to at least one Class 1 or 3 antiarrhythmic medication
  - Paroxysmal: Catheter ablation is recommended* (Class I, Level A).
  - Persistent: Catheter ablation is reasonable (Class IIa, Level B).
  - Longstanding Persistent: Catheter ablation may be considered (Class IIb, Level B).
- Symptomatic AF prior to initiation of antiarrhythmic drug therapy with a Class 1 or 3 antiarrhythmic agent
  - Paroxysmal: Catheter ablation is reasonable (Class IIa, Level B).
  - Persistent: Catheter ablation may be considered (Class IIb, Level C).
  - Longstanding Persistent: Catheter ablation may be considered (Class IIb, Level C).

*Catheter ablation of symptomatic paroxysmal AF is considered a Class I indication only when performed by an electrophysiologist who has received appropriate training and is performing the procedure in an experienced center.

Indications for Concomitant Surgical Ablation of AF

- Symptomatic AF refractory or intolerant to at least one Class 1 or 3 antiarrhythmic medication
  - Paroxysmal: Surgical ablation is reasonable for patients undergoing surgery for other indications (Class IIa, Level C).
  - Persistent: Surgical ablation is reasonable for patients undergoing surgery for other indications (Class IIa, Level C).
  - Longstanding Persistent: Surgical ablation is reasonable for patients undergoing surgery for other indications (Class IIa, Level C).
- Symptomatic AF prior to initiation of antiarrhythmic drug therapy with a Class 1 or 3 antiarrhythmic agent
  - Paroxysmal: Surgical ablation is reasonable for patients undergoing surgery for other indications (Class IIa, Level C).
  - Persistent: Surgical ablation is reasonable for patients undergoing surgery for other indications (Class IIa, Level C).
  - Longstanding Persistent: Surgical ablation may be considered for patients undergoing surgery for other indications (Class IIb, Level C).

Indications for Stand Alone Surgical Ablation of AF

- Symptomatic AF refractory or intolerant to at least one Class 1 or 3 antiarrhythmic medication
  - Paroxysmal: Stand alone surgical ablation may be considered for patients who have not failed catheter ablation but prefer a surgical approach (Class IIb, Level C).
  - Paroxysmal: Stand alone surgical ablation may be considered for patients who have failed one or more attempts at catheter ablation (Class IIb, Level C).
  - Persistent: Stand alone surgical ablation may be considered for patients who have not failed catheter ablation but prefer a surgical approach (Class IIb, Level C).
  - Persistent: Stand alone surgical ablation may be considered for patients who have failed one or more attempts at catheter ablation (Class IIb, Level C).
  - Longstanding Persistent: Stand alone surgical ablation may be considered for patients who have not failed catheter ablation but prefer a surgical approach (Class IIb, Level C).
  - Longstanding Persistent: Stand alone surgical ablation may be considered for patients who have failed one or more attempts at catheter ablation (Class IIb, Level C).
- Symptomatic AF prior to initiation of antiarrhythmic drug therapy with a Class 1 or 3 antiarrhythmic agent
  - Paroxysmal: Stand alone surgical ablation is not recommended (Class III, Level C).
  - Persistent: Stand alone surgical ablation is not recommended (Class III, Level C).
  - Longstanding Persistent: Stand alone surgical ablation is not recommended (Class III, Level C).

<u>Recommendations Regarding Ablation Technique</u>

- Ablation strategies that target the pulmonary veins (PVs) and/or PV antrum are the cornerstone for most AF ablation procedures.
- If the PVs are targeted, electrical isolation should be the goal.
- Achievement of electrical isolation requires, at a minimum, assessment and demonstration of entrance block into the PV.
- Monitoring for PV reconduction for 20 minutes following initial PV isolation should be considered.
- For surgical PV isolation, entrance and/or exit block should be demonstrated.
- Careful identification of the PV ostia is mandatory to avoid ablation within the PVs.
- If a focal trigger is identified outside a PV at the time of an AF ablation procedure, ablation of that focal trigger should be considered.
- If additional linear lesions are applied, operators should consider using mapping and pacing maneuvers to assess for line completeness.
- Ablation of the cavotricuspid isthmus is recommended in patients with a history of typical atrial flutter or inducible cavotricuspid isthmus dependent atrial flutter.
- If patients with longstanding persistent AF are approached, operators should consider more extensive ablation based on linear lesions or complex fractionated electrograms.
- It is recommended that radiofrequency (RF) power be reduced when creating lesions along the posterior wall near the esophagus.

<u>Anticoagulation Strategies: Pre, During, and Post Ablation</u>

Pre Ablation

- Anticoagulation guidelines that pertain to cardioversion of AF should be adhered to in patients who present for an AF ablation in atrial fibrillation at the time of the procedure. In other words, if the patient has been in AF for 48 hours or longer or for an unknown duration,

three weeks of systemic anticoagulation at a therapeutic level are required prior to the procedure, and if this is not the case, a transesophageal echocardiogram (TEE) performed to screen for thrombus is advised. Furthermore, each of these patients will be anticoagulated systemically for two months post ablation.

- Prior to undergoing an AF ablation procedure a TEE should be performed in all patients with atrial fibrillation more than 48 hours in duration or of an unknown duration if adequate systemic anticoagulation has not been maintained for at least 3 weeks prior to the ablation procedure.
- Performance of a TEE in patients who are in sinus rhythm at the time of ablation or patients with AF who are in AF but have been in AF for 48 hours or less prior to AF ablation may be considered but is not mandatory.
- The presence of a left atrial thrombus is a contraindication to catheter ablation of AF.
- Performance of catheter ablation of AF on a patient who is therapeutically anticoagulated with warfarin should be considered.

During Ablation

- Heparin should be administered prior to or immediately following transseptal puncture during AF ablation procedures and adjusted to achieve and maintain an activated clotting time (ACT) of 300 to 400 seconds.
- Performance of AF ablation in a patient systemically anticoagulated with warfarin does not alter the need for intravenous heparin to maintain a therapeutic ACT during the procedure.
- Administration of protamine following ablation to reverse heparin should be considered.

Post Ablation

- In patients who are not therapeutically anticoagulated with warfarin at the time of AF ablation, low molecular weight heparin or intravenous heparin should be used as a bridge to resumption of systemic anticoagulation with warfarin following AF ablation.
- Initiation of a direct thrombin or Factor Xa inhibitor after ablation may be considered as an alternative post procedure anticoagulation strategy.
- Because of the increased risk of post procedure bleeding on full dose low molecular weight heparin (1 mg/kg bid) a reduction of the dose to 0.5 mg/kg should be considered.
- Systemic anticoagulation with warfarin or a direct thrombin or Factor Xa inhibitor is recommended for at least two months following an AF ablation procedure.
- Decisions regarding the continuation of systemic anticoagulation agents more than two months following ablation should be based on the patient's risk factors for stroke and not on the presence or type of AF.
- Discontinuation of systemic anticoagulation therapy post ablation is not recommended in patients who are at high risk of stroke as estimated by currently recommended schemes (cardiac failure, hypertension, age, diabetes, stroke [doubled] [$CHADS_2$] or cardiac failure, hypertension, age ≥75 [doubled], diabetes, stroke [doubled]-vascular disease, age 65–74 and sex category [female] [CHA_2DS_2VASc]).
- Patients in whom discontinuation of systemic anticoagulation is being considered should consider undergoing continuous electrocardiogram (ECG) monitoring to screen for asymptomatic AF/atrial flutter (AFL)/atrial tachycardia (AT).

Definitions:

Level of Evidence

Level A: The data were derived from multiple randomized clinical trials or meta-analyses (of selected studies) or selected meta-analyses.

Level B: The data were derived from a single randomized trial or nonrandomized studies.

Level C: The primary source of the recommendation was consensus opinion, case studies, or standard of care. For certain conditions for which inadequate data are available, recommendations are based on expert consensus and clinical experience and ranked as Level C.

Class of Recommendation

Class I: The benefits of the atrial fibrillation (AF) ablation procedure markedly exceed the risks, and AF ablation should be performed.

Class IIa: The benefits of an AF ablation procedure exceed the risks, and it is reasonable to perform AF ablation.

Class IIb: The benefit of AF ablation is greater or equal to the risks, and AF ablation may be considered.

Class III: AF ablation is of no proven benefit and is not recommended.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Atrial fibrillation

Guideline Category

Evaluation

Management

Treatment

Clinical Specialty

Cardiology

Family Practice

Internal Medicine

Thoracic Surgery

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To provide a state-of-the-art review of the field of catheter and surgical ablation of atrial fibrillation
- To report the findings of a Task Force charged with defining the indications, techniques, and outcomes of this procedure
- To improve patient care by providing a foundation of knowledge for those involved with catheter ablation of atrial fibrillation

Target Population

Patients with atrial fibrillation who are candidates for catheter or surgical ablation

Interventions and Practices Considered

1. Patient selection for catheter ablation of atrial fibrillation
2. Patient selection for surgical ablation (concomitant or stand-alone) of atrial fibrillation
3. Ablation techniques
4. Anticoagulation strategies pre-, during, and post-ablation, including transesophageal echocardiography (TEE) to screen for thrombus before

ablation

Major Outcomes Considered

- Safety of catheter or surgical ablation
- Efficacy/success rate of catheter or surgical ablation, as assessed by:
  - Freedom from symptomatic atrial fibrillation (AF) during follow-up
  - Freedom from symptomatic and asymptomatic AF during follow-up
  - Rate of reduction of AF burden
  - Proportion of patients free of AF
- Reduction in the risk of stroke
- Recurrence of AF
- Adverse effects and complications of AF
- Quality of life
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The Medline and PubMed databases were searched. All initial literature searches were performed at the time the document writing committee was initiated in January of 2011. Subsequent literature searches were performed as needed throughout document development and concluded in February of 2012. All randomized and observational studies in humans were included in literature searches. Initial search terms of atrial fibrillation and catheter ablation, and atrial fibrillation and surgical ablation were used; each section author was responsible for adding search criteria relevant to their section.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Level of Evidence

Level A: The data were derived from multiple randomized clinical trials or meta-analyses (of selected studies) or selected meta-analyses.

Level B: The data were derived from a single randomized trial or nonrandomized studies.

Level C: The primary source of the recommendation was consensus opinion, case studies, or standard of care. For certain conditions for which inadequate data are available, recommendations are based on expert consensus and clinical experience and ranked as Level C.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

The committee reviewed and ranked evidence supporting current recommendations. The grading system for indication level of class of evidence was adapted based on that used by the American College of Cardiology and the American Heart Association.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

In writing a "consensus" document, it is recognized that consensus does not mean that there was complete agreement among all Task Force members. Surveys of the entire Task Force were used to identify areas of consensus and also to develop recommendations concerning the indications for catheter and surgical atrial fibrillation ablation. The indications for catheter and surgical ablation of atrial fibrillation are presented with a class and grade of recommendation to be consistent with what the reader is used to seeing in guideline statements. However, it is important to state that the consensus document is not a guideline.

The Task Force writing group was composed of experts representing seven organizations: the American College of Cardiology (ACC), the American Heart Association (AHA), the Asia Pacific Heart Rhythm Society (APHRS), the European Cardiac Arrhythmia Society (ECAS), the European Heart Rhythm Association (EHRA), the Society of Thoracic Surgeons (STS), and the Heart Rhythm Society (HRS).

Rating Scheme for the Strength of the Recommendations

Class of Recommendation

Class I: The benefits of the atrial fibrillation (AF) ablation procedure markedly exceed the risks, and AF ablation should be performed.

Class IIa: The benefits of an AF ablation procedure exceed the risks, and it is reasonable to perform AF ablation.

Class IIb: The benefit of AF ablation is greater than or equal to the risks, and AF ablation may be considered.

Class III: AF ablation is of no proven benefit and is not recommended.

Cost Analysis

Cost-effectiveness of Atrial Fibrillation (AF) Ablation

Several studies have described the costs of catheter ablation of AF, but few data are available on cost-effectiveness. Radiofrequency catheter ablation of paroxysmal AF was demonstrated in one study to significantly reduce health care resource utilization, with a reduction in the annual cost of health care (not including procedural costs) from a mean of $1,920 ± $889 pre-ablation to $87 ± $68 post-ablation. In that study, the procedural cost of ablation was approximately $17,000 (2001 dollars), an amount considerably lower than the total charges for the procedure, which typically are greater than $50,000 in the United States. Another study retrospectively compared the costs of radiofrequency catheter ablation and drug therapy in patients with paroxysmal AF. In that study, the initial cost of catheter ablation was approximately 4,700 Euros (2001 Euros), then approximately 450 Euros/year afterward. In comparison, the mean annual cost of pharmacological management before catheter ablation was approximately 1,600 Euros, suggesting that the total costs of radiofrequency catheter ablation would be lower than the cost of medical management after five years. However, the mean duration of follow-up was less than one year, and the cost of redo procedures for late recurrences of AF were not considered in the analysis.

Only one study formally analyzed the cost-effectiveness of catheter ablation compared to amiodarone therapy and a rate-control strategy. This study was performed using a Markov decision analysis model. Among 65-year-old patients at moderate risk of stroke, the incremental cost-

effectiveness ratio (ICER) of catheter ablation was $51,800 (2004 dollars) per quality-adjusted life-year (QALY). In 55-year-old patients at moderate risk of stroke, catheter ablation had an ICER of $28,700 per QALY compared to rate control. However, in patients with no risk factors for stroke, catheter ablation had an ICER of $98,900 per QALY. Further analysis indicated that in 65-year-old patients at moderate risk of stroke and with an 80% one-year success rate of catheter ablation, the relative risk of stroke after catheter ablation would need to decrease by ≥42% compared with anticoagulated patients in AF for the ICER of catheter ablation to be <$50,000. Of note is that $50,000 generally is considered to be the threshold value for cost-effectiveness of a therapy. However, the model assumed that successful ablation of AF eliminates the excess risk of stroke, which is yet to be proven in a prospective study.

The limited data available on cost-effectiveness suggest that catheter ablation of AF may be cost-effective in patients with one or more risk factors for stroke but not in patients who have no risk factors.

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

Not stated

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate patient selection, procedural techniques, patient management and follow-up for use of catheter and surgical ablation of atrial fibrillation

Potential Harms

- Major complications and serious adverse effects, including:
  - Atrio esophageal fistula
  - Bleeding, including bleeding following cardiac surgery
  - Cardiac perforation/tamponade
  - Deep sternal wound infection/mediastinitis following cardiac surgery
  - Esophageal injury
  - Gastric motility/pyloric spasm disorders
  - Mediastinitis
  - Myocardial infarction in the context of atrial fibrillation ablation
  - Pericarditis
  - Phrenic nerve paralysis
  - Pulmonary vein stenosis
  - Silent cerebral embolism
  - Stroke or transient ischemic event post ablation
  - Unanticipated adverse device effect
  - Vagal nerve injury

    - Vascular access complication
    - Perioperative, postoperative, early, and late mortality
- Required pacemaker placement

Contraindications

Contraindications

The presence of a left atrial thrombus is a contraindication to catheter ablation of atrial fibrillation.

Qualifying Statements

Qualifying Statements

- Despite a large number of authors, the participation of several societies and professional organizations, and the attempts of the group to reflect the current knowledge in the field adequately, this document is not intended as a guideline. Rather, the guideline authors would like to refer to the current guidelines on atrial fibrillation (AF) management for the purpose of guiding overall AF management strategies. This Consensus Document is specifically focused on catheter and surgical ablation of AF, which the guideline authors recognize is relevant for only a small portion of the population affected by AF.
- This statement is not intended to recommend or promote catheter ablation of AF. Rather the ultimate judgment regarding care of a particular patient must be made by the health care provider and patient in light of all the circumstances presented by that patient.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Identifying Information and Availability

Bibliographic Source(s)

Calkins H, Kuck KH, Cappato R, Brugada J, Camm AJ, Chen SA, Crijns HJ, Damiano RJ Jr, Davies DW, DiMarco J, Edgerton J, Ellenbogen K, Ezekowitz MD, Haines DE, Haissaguerre M, Hindricks G, Iesaka Y, Jackman W, Jalife J, Jais P, Kalman J, Keane D, Kim YH, Kirchhof P, Klein G, Kottkamp H, Kumagai K, Lindsay BD, Mansour M, Marchlinski FE, McCarthy PM, Mont JL, Morady F, Nademanee K, Nakagawa H, Natale A, Nattel S, Packer DL, Pappone C, Prystowsky E, Raviele A, Reddy V, Ruskin JN, Shemin RJ, Tsao HM, Wilber D, Heart Rhythm Society Task Force on Catheter and Surgical Ablation of Atrial Fibrillation. 2012 HRS/EHRA/ECAS expert consensus statement on catheter and surgical ablation of atrial fibrillation: recommendations for patient selection, procedural techniques, patient management and follow-up, definitions, endpoints, and research trial design. Heart Rhythm. 2012 Apr;9(4):632-96.e21. [736 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Apr

Guideline Developer(s)

European Cardiac Arrhythmia Society - Disease Specific Society

European Heart Rhythm Association - Professional Association

Heart Rhythm Society - Professional Association

Source(s) of Funding

Heart Rhythm Society

Guideline Committee

Task Force on Catheter and Surgical Ablation of Atrial Fibrillation

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Financial Disclosures/Conflicts of Interest

All members of the Task Force, as well as peer reviewers of the document, were asked to provide disclosure statements for all relationships that might be perceived as real or potential conflicts of interest. These tables are shown at the end of the original consensus statement.

Guideline Endorser(s)

American College of Cardiology Foundation - Medical Specialty Society

American Heart Association - Professional Association

Asia Pacific Heart Rhythm Society - Disease Specific Society

Society of Thoracic Surgeons - Medical Specialty Society

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the Heart Rhythm Society (HRS) Web site .

Availability of Companion Documents

The following is available:

- The HRS policy for development and endorsement of clinical guidance documents from HRS and others. Washington (DC): Heart Rhythm Society (HRS); 2009 Sep. 6 p. Available from the Heart Rhythm Society Web site .

Patient Resources

The following is available:

- Catheter ablation. Available from the Heart Rhythm Society Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on February 13, 2013. This summary was updated by ECRI Institute on March 10, 2014 following the U.S. Food and Drug Administration advisory on Low Molecular Weight Heparins.

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